

Attorney/Docket No. 28758.65  
Customer No. 000027683

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Khosravi, et al.

Serial No:

10/092,769

Filed:

March 7, 2002

For:

INSULIN-LIKE GROWTH FACTOR  
SYSTEM AND CANCER

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Group Art Unit:

1642

Examiner:

Unknown

1642  
10/092,769

RECEIVED

INFORMATION DISCLOSURE STATEMENT

Commissioner For Patents  
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 CFR §1.56, and in accordance with the practice under 37 CFR §1.97 and §1.98, the Examiner's attention is directed to the documents listed on the enclosed modified Form PTO-1449. No inference should be made that the cited references are in fact material, are in fact prior art, or that no better art exists. The cited patents are listed in numerical order and are not in any order based on their pertinence. Copies of the listed information are attached.

This Information Disclosure Statement is being filed within three months of the United States filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required (37 CFR §1.97(b)).

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 08-1394.

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Respectfully submitted,

Brian J. Hubbard  
Reg. No. 45,873

Date:

April 30, 2002

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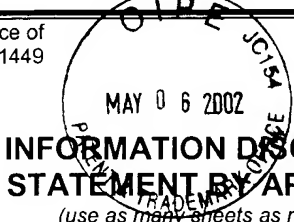
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SANDRA KUBIN

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In place of PTO-1449 Form				Complete if Known	
 <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)</p>				Application Number	10/092,769
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				Applicant(s)	Khosravi, et al.
				Art Unit	1642
				Examiner Name	Unknown
SHEET	1	OF	8	Attorney Docket Number	28758.65

U. S. PATENT DOCUMENTS				
Examiner's Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	A1	5,614,372	03-25-1997	Lilja, et al.

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Cite No.	Foreign Patent Document (Country Code - Number - Kind)	Publication Date MM-DD-YYYY	Patentee or Applicant of Cited Document	Translation Y/N
	B1	WO 96/26442	08-29 1996	Lilja, et al.	
	B2	EP 0 811 164 B1	01-09-2002	Lilja, et al.	

OTHER PRIOR ART		
Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, title of the item, date, page(s), volume-issue number(s), publisher, city/country where published
	C1	Albanes, "Total Calories, Body Weight, and Tumor Incidence in Mice", Cancer Research 47: 1987-1992 (April 15, 1987)
	C2	Andersson et al., "Body Size and Prostate Cancer: a 20-year Follow-up Study Among 135006 Swedish Construction Workers", J. National. Cancer Institute, 89(5) 385-389-9 (1997) Abstract Only.
	C3	Aquilina et al., "Androgen Deprivation as a Strategy for Prostate Cancer Chemoprevention", J. Natl. Cancer Institute, 89(10): 689-696 (1997) Abstract Only.
	C4	Arteaga et al., "Blockade of the Type I Somatomedin Receptor Inhibits Growth of Human Breast Cancer Cells in Athymic Mice", J. Clin. Invest., Vol. 84: 1418-1423 (November 1989)
	C5	Avila et al., "Sequence Determination of Variable Region Genes of Two Human Monoclonal Antibodies Against <i>Neisseria meningitidis</i> ", Gene 92, 127: 237-274 (1993)
	C6	Azmi et al., "Variable Region Sequences and Idiotype Expression of a Protective Human Immunoglobulin M Antibody to Capsular Polysaccharides of <i>Neisseria meningitidis</i> Group B and <i>Escherichia coli</i> K1", Infection and Immunity, 62(5): 1776-1786 (May 1994)
	C7	Barni et al., "Serum Levels of Insulin-Like Growth Factor-I in Operable Breast Cancer in Relation to the Main Prognostic Variables and Their Perioperative Changes in Relation to Those of Prolactin", Tumori, 80: 212-215 (1994)
	C8	Bates et al., "Mammary Cancer in Transgenic Mice Expressing Insulin-Like Growth Factor II (IGF-II), British Journal of Cancer, 72: 1189-1193 (1995)
	C9	Boyle et al., "Geographical and Temporal Patterns of Incidence and Mortality From Prostate Cancer", Urology, 46(3 Suppl. A) 47-55 (1995) Abstract Only.
	C10	Bruning et al., "Insulin-like Growth-Factor-Binding Protein 3 Decreased in Early-Stage Operable Pre-Menopausal Breast Cancer, Int'l. J. Cancer, 62: 266-270 (1995)
	C11	Campagnoli et al., "Differential Effects of Oral Conjugated Estrogens and Transdermal Estradiol on Insulin-Like Growth Factor 1, Growth Hormone and Sex Hormone Binding Globulin Serum Levels", Gynecol. Endocrinol., 7: 251-258 (1993)

Examiner Signature		Date Considered	
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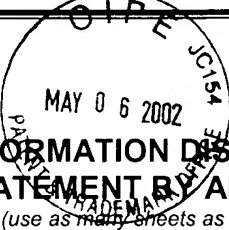
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	C12	Canobbio et al., "Somatuline (BIM 23014) and Tamoxifen Treatment of Postmenopausal Breast Cancer Patients: Clinical Activity and Effect on Insulin-Like Growth Factor-I (IGF-I) Levels", <i>Anticancer Res.</i> 15(6B): 2687-2690 (November-December 1995)
	C13	Chen, et al., "Co-Expression of Bovine Growth Hormone (GH) and Human GH Antagonist Genes in Transgenic Mice", <i>Endocrinology</i> , 138(2): 851-854 (1997)
	C14	Cohen et al., "Cell Proliferation in Carcinogenesis", <i>Science</i> , 249(4972): 1007-1005 (1990) Abstract Only.
	C15	Cohen et al., "Genetic Errors, Cell Proliferation, and Carcinogenesis", <i>Cancer Research</i> , 51: 6493-6505 (1991)
	C16	Cohen et al., "Insulin-like Growth Factors (IGFs), IGF Receptors, and IGF-Binding Proteins in Primary Cultures of Prostate Epithelial Cells", <i>J. Clinical Endocrinal Metab.</i> , 73(2): 401-407 (1991) Abstract Only
	C17	Cohen, et al., "The IGF Axis in the Prostate", <i>Hormone Metab. Research</i> , 26(2): 81-84 (1994) Abstract Only.
	C18	Culig et al., "Androgen Receptor Activation in Prostatic Tumor Cell Lines by Insulin-Like Growth Factor-I, Keratinocyte Growth Factor, and Epidermal Growth Factor", <i>Cancer Research</i> , 54(20): 5474-5478 (1994) Abstract Only.
	C19	Del Giudice et al., "Insulin and Related Factors in Premenopausal Breast Cancer Risk", <i>Breast Cancer Research and Treatment</i> , 47: 111-120 (1998)
	C20	Favoni et al., "Insulin-Like Growth Factor-I (IGF-I) and IGF-Binding Proteins Blood Serum Levels in Women with Early and Late-Stage Breast Cancer: Mutual Relationship and Possible Correlations with Patients' Hormonal Status", <i>J. Cancer Res. Clin. Oncol.</i> , 121(11): 674-682 (1995)
	C21	Final Report on the Aspirin Component of the Ongoing Physicians' Health Study Steering Committee of the Physicians' Health Study Research Group", <i>N. Engl J. of Medicine</i> , 321(3): 129-135 (1989) Abstract Only.
	C22	Finne et al., "Insulin-Like Growth Factor I is Not a Useful Marker of Prostate Cancer in Men with Elevated Levels of Prostate-Specific Antigen", <i>The Journal of Clinical Endocrinology &amp; Metabolism</i> , 85(8): 2744-2747 (2000)
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	C24	Frost et al., "Changes in the Insulin-Like Growth Factor (IGF), Insulin-Like Growth Factor Binding Protein (IGFBP) & IGFBP Protease Status with Endocrine Therapy for Breast Cancer", <i>Journal of Endocrinology</i> , Vol. 139: 102 (1993)
	C25	Gann et al., "Prospective Study of Sex Hormone Levels and Risk of Prostate Cancer", <i>J. Natl. Cancer Institute</i> , 88(16): 1118-1126 (1996) Abstract Only.
	C26	Gann et al., "A Prospective Evaluation of Plasma Prostate-Specific Antigen for Detection of Prostatic Cancer", <i>JAMA</i> 273(4): 289-294 (1995) Abstract Only.
	C27	Giovannucci et al., "The CAG Repeat Within the Androgen Receptor Gene and Its Relationship to Prostate Cancer", <i>Proc. Natl. Acad Sci USA</i> , 94(15): 8272 (1997) Abstract Only.

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	C28	Goodman-Gruen et al., "Epidemiology of Insulin-Like Growth Factor-I in Elderly Men and Women. The Rancho Bernardo Study", Am. J. Epidemiol., 146(4): 357 (1997) Abstract Only.
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	C30	Hadsell et al., "Targeted Expression of des (1-3) Human Insulin-Like Growth Factor I in Transgenic Mice Influences Mammary Gland Development and IGF-Binding Protein Expression", Endocrinology, 137(1): 321-330 (1996)
	C31	Hankinson, et al., "Alcohol, Height and Adiposity in Relation to Estrogen and Prolactin Levels in Postmenopausal Women", Journal of the National Cancer Institute, 87(17): 1297-1302 (September 6, 1995)
	C32	Hebert et al., "Adult Height and Incidence of Cancer in Male Physicians (United States), Cancer Causes Control, 8(4): 591-597 (1997) Abstract Only.
	C33	Helle et al., "Influence of Droloxifene on Plasma Levels of Insulin-Like Growth Factor (IGF)-1, Pro-IGF-IIIE, Insulin-Like Growth Factor Binding Protein (IGFBP)-1 and IGFBP-3 in Breast Cancer Patients", Steroid Biochem. Molec. Bio., 57(3/4): 167-171 (1996)
	C34	Helle et al., "Insulin-Like Growth Factors in Breast Cancer", Acta Oncol., Vol. 35, Suppl. 5: 19-22 (1996)
	C35	Ho et al., "Insulin-Like Growth Factor-Binding Protein-2 in Patients With Prostate Carcinoma and Benign Prostatic Hyperplasia", Clinical Endocrinology, 46: 333-342 (1997)
	C36	Ho et al., "Tamoxifen Alters Serum Insulin-Like Growth Factors and Binding Proteins in Postmenopausal Breast Cancer Patients", 46(1): 112 (1997)
	C37	Holly et al., "Insulin-Like Growth Factor Binding Proteins: A Review of Methodological Aspects of Their Purification, Analysis and Regulation", 3 <sup>rd</sup> International Symposium on Insulin-Like Growth Factors, pg. 20-30
	C38	Hsing et al., " Regulation of Apoptosis Induced by Transforming Growth Factor-Beta 1 in Nontumorigenic Rat Prostatic Epithelial Cell Lines", Cancer Research, 56(22): 5146-5149 (1996) Abstract Only.
	C39	Hunter et al., "Diet, Body Size, and Breast Cancer", Epidemiologic Reviews, 15(1): 110-132 (1993)
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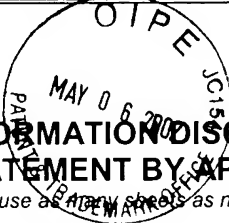
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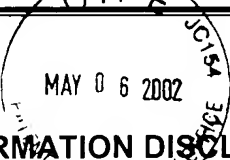
	C43	Huynh et al., "Estradiol and Antiestrogens Regulate a Growth Inhibitory Insulin-Like Growth Factor Binding Protein 3 Autocrine Loop in Human Breast Cancer Cells", The Journal of Biological Chemistry, 271(2): 1016-1021 (1996).
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	C47	Jones et al., "Insulin-Like Growth Factors and Their Binding Proteins: Biological Actions", Endocrine Reviews, 16(1): 3-34 (1995)
	C48	Juul et al., "Serum Insulin-Like Growth Factor-I in 1030 Healthy Children, Adolescents, and Adults: Relation to Age, Sex, Stage of Puberty, Testicular Size, and Body Mass Index", J. Of Clinical Endocrinology and Metabolism, 78(3): 744-752 (1994)
	C49	Juul et al., "Serum Levels of Insulin-Like Growth Factor (IGF)-Binding Protein-3 (IGFBP-3) in Healthy Infants, Children, and Adolescents: The Relation to IGF-I, IGF-II, IGFBP-1, IGFBP-2, Age, Sex, Body Mass Index, and Pubertal Maturation", J. of Clinical Endocrinology and Metabolism, 80(8): 2534-2542 (1995)
	C50	Kazer, "Insulin resistance, Insulin-Like Growth Factor I and Breast Cancer: A Hypothesis", Int. J. Cancer, 62(4): 403-406 (August 9, 1995)
	C51	Kleinberg, "Role of IGF-I in Normal Mammary Development", Breast Cancer Research and Treatment, Vol. 47: 201-208 (1998)
	C52	Khosravi MJ, et al., "Development of a Non-Competitive Immunoassay for Human Insulin-Like Growth Factor-II in Serum. Abstract Presented at the 10 <sup>th</sup> International Congress of Endocrinology; P1-551 (1996)
	C53	Lahti et al., "Plasma Insulin-Like Growth Factor I and Its Binding Proteins 1 and 3 in Postmenopausal Patients with Breast Cancer Receiving Long Term Tamoxifen", 74(2): 618-624 (July 15, 1994)
	C54	Lamson et al., "Insulin-Like Growth Factor Binding Proteins: Structural and Molecular Relationships", Growth Factors, 5(1): 19-28 (1991)
	C55	Lassarre et al., "Serum Insulin-Like Growth Factors and Insulin-Like Growth Factor Binding Proteins in the Human Fetus. Relationships with Growth in Normal Subjects with Intrauterine Growth Retardation", Pediatric Res., 29(3): 219-225 (1991) Abstract Only.
	C56	La Vecchia et al., "Height and Cancer Risk in a Network of Case-Control Studies From Northern Italy, " Interrogatory. J. Cancer, 45(2): 275-279 (1990) Abstract Only.
	C57	Lash, "Insulin-like Growth Factor I and Prostate Cancer Risk: A Population-Based, Case-Control Study", J. Nat'l. Cancer Institute, 90(23), 1841-1842 (1998)

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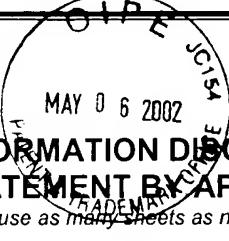
	C58	Lee et al., "Insulin-Like Growth Factors and Breast Cancer", Biomedicine & Pharmacotherapy, 49(9): 415-421 (1995)
	C59	Lee et al., "IGF System Components as Prognostic Markers in Breast Cancer", Breast Cancer Research and Treatment, Vol. 47: 295-302 (1998)
	C60	Lonning et al., "Influence of Tamoxifen on Plasma Levels of Insulin-Like Growth Factor I and Insulin-Like Growth Factor Binding Protein I in Breast Cancer Patients", Cancer Research 52: 4719-4723 (September 1, 1992)
	C61	Lonning et al., "Relations Between Sex Hormones, Sex Hormone Binding Globulin, Insulin-Like Growth Factor-I and Insulin-Like Growth Factor Binding Protein-1 in Post-Menopausal Breast Cancer Patients", Clinical Endocrinology, 42(1): 23-30 (1995)
	C62	Lucas et al., "Age-Dependent V Region Expression in the Human Antibody Response to the <i>Haemophilus influenzae</i> Type b Polysaccharide", The Journal of Immunology, 150(5): 2056-2061, No. 1.5 (March 1, 1993)
	C63	Malaab et al., "Direct Effects of Tamoxifen on Growth Hormone Secretion by Pituitary Cells <i>in vitro</i> ", Eur. J. Cancer, 28A(45): 788-793 (1992)
	C64	Mantzoros et al., "Insulin-Like Growth Factor 1 in Relation to Prostate Cancer and Benign Prostatic Hyperplasia", British Journal of Cancer, 76(9): 1115-1118 (1997)
	C65	Marshall et al., "Risk of Breast Cancer Associated with Atypical Hyperplasia of Lobular and Ductal Types", Cancer Epidemiology Biomarkers & Prevention, 6: 2970391 (May 1997)
	C66	Meredith, "Finding From Asia, Australia, Europe, and North America on Secular Change in Mean Height of Children, youths, and Young Adults". Am. J. Phys. Anthropol., 44(2): 315-325 (1976) Abstract Only.
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	C68	Miglietta et al., "Suramin and Serum Insulin-Like Growth Factor Levels in Metastatic Cancer Patients", Anticancer Research, 13:2473-2476 (1993).
	C69	Oates et al., "The Mannose 6-Phosphate/Insulin-Like Growth Factor 2 Receptor (M6P/IGF2R), a Putative Breast Tumor Suppressor Gene", Breast Cancer Research and Treatment, Vol. 47: 269-281 (1998)
	C70	Oh et al., "Transforming Growth Factor $\beta$ -Induced Cell Growth Inhibition in Human Breast Cancer Cells in Mediated Through Insulin-Like Growth Factor-Binding Protein-3 Action", The Journal of Biological Chemistry, 270(23): 13589-13592 (1995)
	C71	Oh, "IGF-Independent Regulation of Breast Cancer Growth by IGF Binding Proteins", Breast Cancer Research and Treatment, Vol. 47: 283-293 (1998)
	C72	Osorio et al., "Insulin-Like Growth Factors (IGFs) and IGF binding proteins-1, -2, and -3 in Newborn Serum: Relationships to Fetoplacental Growth at Term", Early Human Development 46: 15-26 (1996)
	C73	Papa et al., "Insulin-Like Growth Factor-I Receptors are Overexpressed and Predict a Low Risk in Human Breast Cancer", Cancer Res., 53(16): 3736-3740 (August 15, 1993)

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	C74	Pariza et al., "Historical Perspective: Calories and Energy Expenditure in Carcinogenesis", American Journal of Clinical Nutrition, 45: 151-156 (1987)
	C75	Parrillo, "The Effect of Low-Dose Warfarin on the Risk of Stroke in Patients with NonRhumatic Atrial Fibrillation", The New England Journal of Medicine, 323(22): 1560-1562 (November 29, 1990)
	C76	Peyrat et al., "Insulin-Like Growth Factor 1 Receptors (IGF1-R) and IGF1 in Human Breast Tumors", J. Steroid Biochem. Molec. Biol., 37(6): 823-827 (1990)
	C77	Peyrat, et al., "Plasma Insulin-Like Growth Factor-1 (IGF-1) Concentrations in Human Breast Cancer", Eur. J. Cancer, 29A(4): 492-497 (1993)
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	C79	Peyrat et al., "Plasma Insulin-Like Growth Factor in Primary Breast Cancer Patients Treated with Adjuvant Chemotherapy", British Journal of Cancer, 77(10): 1669-1671 (1998)
	C80	Pollak et al., "Somatostatin Analogue SMS 201-995 Reduces Serum IGF-I Levels in Patients With Neoplasms Potentially Dependent on IGF-I", Anticancer Research, 9(4): 889-891 (1989) Abstract Only.
	C81	Pollak et al., "Effect of Tamoxifen on Serum Insulin-Like Growth Factor I Levels in Stage I Breast Cancer Patients", Journal of the National Cancer Institute., 82(21): 1693-1697 (November 7, 1990)
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	C84	Pollak et al., "Relationship of Circulating Insulin-Like Growth Factor I Level to Breast Cancer Risk", 4 <sup>th</sup> International Symposium on Insulin-Like Growth Factors, C29 (1997)
	C85	Pollak, "Endocrine Effects of IGF-I on Normal and Transformed Breast Epithelial Cells: Potential Relevance to Strategies for Breast Cancer Treatment and Prevention", Breast Cancer Research and Treatment, 47: 209-217 (1998)
	C86	"Prostate Cancer: Progress in Screening, Prevention Holds Promise", Harvard Health Letter, 23(9): 4-5 (1998)
	C87	Rasmussen et al., "Paracrine/Autocrine Regulation of Breast Cancer by the Insulin-Like Growth Factors", Breast Cancer Research and Treatment, 47: 219-233 (1998)
	C88	Rechler, "Editorial: Growth Inhibition by Insulin-Like Growth Factor (IGF) Binding Protein-3 - What's IGF Got To Do With It?", Endocrinology, 138(7): 2645-2647 (1997)
	C89	Rocha et al., "Levels of Insulin-Like Growth Factor Binding Protein 3 (BP3) and its mRNA Correlate in Human Breast Cancer", Breast Cancer Research and Treatment, 32: 57 (1994)

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	C90	Rocha et al., "Insulin-Like Growth Factor Binding Protein-3 (IGFBP3) and Insulin Receptor Substrate (IRS1) in Primary Breast Cancer: Larger Tumors Have Higher BP3 Levels and Higher Levels of IRS1 are Associated with Lower Disease-Free Survival (DFS) rate", <i>Breast Cancer Research and Treatment</i> , 37: 55 (1996)
	C91	Rosner, "Multivariate Methods in Ophthalmology with Application to Other Paired-Data Situations", <i>Biometrics</i> 40: 1025-1035 (December 1984)
	C92	Rozen et al., "Antiproliferative Action of Vitamin D-Related Compounds and Insulin-Like Growth Factor-Binding Protein 5 Accumulation", <i>Journal of the National Cancer Institute</i> , 89(9): 652-656 (May 7, 1997)
	C93	Ruan et al., "Intact and Amino-Terminally Shortened Forms of Insulin-Like Growth Factor I Induce Mammary Gland Differentiation and Development", <i>Proc. Nat'l. Acad. Sci. USA</i> , Vol. 89: 10872-10876 (November 1992)
	C94	Ruan et al., "Estradiol Enhances the Stimulatory Effect of Insulin-Like Growth Factor-I (IGF-I) on Mammary Development and Growth Hormone-Induced IGF-I Messenger Ribonucleic Acid", <i>Endocrinology</i> 136(3): 1296-1302 (1995)
	C95	Rudman et al., "Effects of Human Growth Hormone in Men Over 60 Years Old", <i>N. Engl. J. Med.</i> , 323(1): 1-6 (1990) Abstract Only
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	C102	Thissen et al., "Nutritional Regulation of the Insulin-Like Growth Factors", <i>Endocrine Reviews</i> , 15(1): 80-101 (February 1994)
	C103	Tibblin et al., "High Birthweight as a Predictor of Prostate Cancer Risk", <i>Epidemiology</i> , 6(4): 423-424 (1995) Abstract
	C104	Tornell et al., "Induction of Mammary Adenocarcinomas in Metallothionein Promoter-Human Growth Hormone Transgenic Mice", <i>Int'l. J. Cancer</i> , 49: 114-117 (1991)

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In place of PTO-1449 Form				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/092,769
				Filing Date	March 7, 2002
				Applicant(s)	Khosravi, et al.
				Art Unit	1642
				Examiner Name	Unknown
SHEET	8	OF	8	Attorney Docket Number	28758.65

	C105	Tornell et al., "High Frequency of Mammary Adenocarcinomas in Metallothionein Promoter-Human Growth Hormone Transgenic Mice Created from Two Different Strains of Mice", J. Steroid Biochem. Molec. Biol., 43(1-3): 237-242 (1992)
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	C117	Zarandi et al., "Synthesis and Biological Activities of Highly Potent Antagonists of Growth Hormone-Releasing Hormone", Proc. Natl. Acad. Sci. USA, 91: 12298-12302 (December 1994).

Examiner Signature		Date Considered	
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